DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 30, 2015

EquipMed North America Incorporated
Mr. Jim Barley
Director of Regulatory Affairs
411 Lucerne Drive #1
Verona, Wisconsin 53593

Re: K141986
Trade/Device Name: ELux810 Medical Laser
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: December 19, 2014
Received: December 24, 2014

Dear Mr. Barley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson
-A

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141986

Device Name

ELux810 Medical Laser

Indications for Use *(Describe)*

The ELux810 Laser is indicated for hair removal, permanent hair reduction in people with Fitzpatrick skin type I-IV. It is also indicated for the treatment of benign superficial vascular and benign superficial pigmented lesions in people with Fitzpatrick skin type I-IV. Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs re-growing when measured at 6, 9 and 12 months after the completion of a treatment regimen.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary K141986

(As required by 21 CFR 807.92(a))

Summary of Safety and Effectiveness for the ELux810 Medical Laser

Date Prepared: January 27, 2015

A. Submitter Information

EquipMed North America, Inc.
411 Lucerne Drive # 1
Verona, WI 53593
Contact: Stene Marshall
Phone Number: 954-643-2510

Trade Name: ELux810 Medical Laser

B. Device Information

Trade/Proprietary Name:	ELux810 Medical Laser
Common name of device:	Semi-Conduct Laser unit
Classification Name:	Powered Laser Surgical Instrument
Product Code:	78 GEX
Regulatory Class:	II
Classification Number:	878.4810
Reason for 510(k):	New device

C.

Primary Predicate Device:	Emvera Diolux Laser
Predicate 510(k) #:	K123257
Predicate product code:	GEX

D. Device Description

The ELux810 Laser is a diode laser of 808nm system. This device is composed of a main body to operate each function of equipment and a hand piece for irradiation of laser, and is designed to use in various treatments by effecting to skin by laser beam of 808nm generated from laser diode. Diode laser of CW system is able to transfer stable and uniform pulses to skin, therefore medical doctor can treat patient safely and effectively using this equipment.

E. Statement of Indications for Use

The ELux810 Laser is indicated for hair removal, permanent hair reduction in people with Fitzpatrick skin type I-IV. It is also indicated for the treatment of benign superficial vascular and benign superficial pigmented lesions in people with Fitzpatrick skin type I-IV. Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs re-growing when measured at 6, 9 and 12 months after the completion of a treatment regimen.

F. Comparison of Required Technological Characteristics:

Information was submitted to demonstrate that there are no significant differences in technological characteristics between the ELux810 Laser, Emvera Diolux Laser (Primary Predicate Device). The following comparison chart shows that the subject device and the predicate device are substantially equivalent:

Parameters	**ELux810 Laser**	**Emvera Diolux Laser**	Determination
Indications for Use	The ELux810 Laser is indicated for hair removal, permanent hair reduction and for the treatment of benign vascular and pigmented lesions.	The Emvera Diolux Laser is indicated for hair removal, permanent hair reduction and for the treatment of benign vascular and pigmented lesions.	Same
Principal of Operation	The laser beams a highly concentrated light into hair follicles. The pigment in the hair follicle absorbs the light which destroys the hair.	The laser beams a highly concentrated light into hair follicles. The pigment in the hair follicle absorbs the light which destroys the hair.	Same

Parameters	ELux810 Laser	Emvera Diolux Laser	Determination
Light Source	Diode (Continuous Wave)	Diode (Continuous Wave)	Same
Wave Length	808 nm	808nm	Same
Laser Diode Power	Max 600w	Max 600w	
Energy Density/Fleunce	Up to 120J/cm2	Up to 120J/cm2	Same
Mode	Pulsed	Pulsed	Same
Pulse Duration	5-625ms	5-625ms	SE
Pulse Repetition Rate (Repetition)	1-2 Hz DP 2 1-6 Hz DP 1 5-10 Hz FDP Mode	1-2 Hz DP 2 1-3 Hz DP 1 5-10 Hz FDP Mode	SE
Spot Size	12 x 11 mm	12 mm (Square)	SE
Cooling	Water Cooling (-5°C~5°C)	Water Cooling (-5°C~5°C)	SE
Optical Guide	Sapphire Crystal	Sapphire Crystal	Same
Power Input	120/230V 20/10 A 50/60 Hz	120/230V 20/10 A 50/60 Hz	

G. Summary and Conclusion of Nonclinical and Clinical Tests:

The ELux810 Laser met the appropriate requirements contained in the following FDA Guidance Documents, Regulations and Standards:

US FDA Guidance Documents

Guidance on the Content and Organization of a Premarket Notification for a Medical Laser (Draft), June 1995

US Regulations

21CFR Part 1040, Sections 1040.10 and 1040.11 with permissible deviations relative to Laser Notice **50,** dated June 24, **2007.**

Recognized Consensus Standards

- **ISO 14971, Second Edition,** 2007-03-01, Medical Devices – Application of Risk Management to Medical Device.

- **IEC 60601-1: 2005** (Third Edition) Medical electrical equipment Part **1:** General requirements for basic safety and essential performance and tested for compliance with all functional requirements,
- **EN 60601-1-2: 2007,** Medical electrical equipment Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests.
- **EN 60601-1-6: 2010,** Medical electrical equipment Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- **IEC 60601-2-**22: **2007** (Third Edition), Medical electrical equipment Part 2: Particular requirements for the safety of diagnostic and therapeutic laser equipment,
- **IEC 60825-1:2007** Safety of Laser Products - Part **1:** Equipment classification, requirements and user's guide,
- **IEC 62304:2006,** Medical device software – Software life cycle processes,
- **IEC 62366-1:2008** Medical Devices – Application of usability engineering to medical devices

H. Discussion of Clinical Tests:

None submitted

I. Conclusions Demonstrating Safety, Effectiveness and Performance:

The ELux810 Laser has been tested and found to meet all product specifications and requirements. The device was tested to all of the appropriate FDA regulations and Consensus Standards and met all requirements. The device labeling met all FDA requirements and the device has the appropriate safety warning labels.

After review of the Risk Analysis, all verification and validation test data and reports, the conclusion of the Design Review Committee was that the ELux810 Laser is safe and effective for its intended use and is substantially equivalent to the predicate device.